

Amendments to the Drawings:

Twelve (12) Replacement Sheets are submitted herewith.

The Replacement Sheets are intended to provide formal (acceptable) drawings to replace the informal drawings originally filed in the application.

The Replacement Sheet showing Figs. 26, 27 and 28 reflects a correction to the lead line for reference numeral 1400 in Figs. 26 and 27. An Annotated Sheet is submitted herewith showing the correction.

The correction is further discussed in the Remarks section of this paper.

Attachments:

Twelve (12) Replacement Sheets

One (1) Annotated Sheet

REMARKS

The above-identified application has been carefully reviewed in light of the Office Action mailed February 23, 2006. Enclosed is a Request for Extension of Time, and required fee, extending the period for responding to the Office Action to and including June 23, 2006.

Submitted herewith, in compliance with 37 CFR 1.121(d), are formal (acceptable) drawings (Replacement Sheets) in the above-identified application. Figs. 26 and 27 have been amended, as shown in the Annotated Sheet (submitted herewith), to make clear that the reference numeral 1400 refers to the appliance rather than to the entire oropharyngeal region including the appliance. Support for these drawing amendments is provided at the first and second full paragraphs of page 46 of the specification.

In view of the formal (acceptable) drawings and the amended drawings as noted above, applicant submits that the drawings, in particular, Fig. 26, facilitate understanding of the invention and meet the requirements of the rules, in particular 37 CFR 1.84 and 1.121(d).

Without conceding to the correctness of any of the Examiner's claim rejections, certain of the present claims have been amended seeking to obtain an early allowance in the above-identified application. Applicant expressly reserves the right to seek patent protection for the previous claims and for any other claims supported by the above-identified application in one or more related applications.

Specifically, claim 52 has been amended to provide that the appliance provided has at least two substantially laterally positioned elements substantially longitudinally spaced apart from each other. Claim 70 has been amended to be consistent

with the amendment to claim 52. In other words, certain of the subject matter from claim 70 has been included in claim 52 and such subject matter has, therefore, been deleted from claim 70. The dependencies of claims 71-76 have been amended to be consistent with the amendment to claim 52. Each of these amendments is fully supported by the present specification.

Claims 52-55, 66-68, 70, 71, 73-77, 79 and 80 have been rejected under 35 U.S.C. 102(b) as being anticipated by Conrad et al (U.S. Patent 6,250,307). Claims 82-90 have been rejected under 35 U.S.C. 102(e) as being anticipated by Metzger et al (U.S. Patent 2003/0149488). Claims 72, 81, 91 and 92 have been rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad et al in view of Metzger et al. Applicant traverses each of these rejections as it pertains to the present claims.

The present claims are directed to methods and apparatus for treating at least one of sleep apnea and snoring in a human or an animal having an oropharyngeal region with lateral and posterior walls.

In independent claim 52, such a method comprises providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal. The appliance so provided has at least two substantially laterally positioned elements substantially longitudinally spaced apart from each other, and is effective in treating at least one of sleep apnea and snoring.

In independent claim 82, such an apparatus for treating at least one of sleep apnea and snoring in a human or animal comprises an appliance comprising two elongated curved elements. Each of the two elements has a substantially circular dimension between a first end and a second end extending through more than

90 degrees of a circle. The two elements are coupled together at respective first and second ends and are spaced apart from each other between the first and second ends. The appliance is sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall. When the appliance is so placed, it is effective in treating at least one of sleep apnea and snoring.

In order to facilitate the Examiner's understanding of the present invention, please consider the following. As set forth at page 17, lines 23-25 of the specification, Fig. 26 shows a simplified view of the oropharyngeal region having various apparatus of the invention implanted therein. Thus, the appliance 1400 shown implanted in the oropharyngeal region 1a in Fig. 26 can be considered to be generic to various appliances disclosed in the above-identified application. The apparatus 10f of elected Fig. 7 is one of these apparatus. In other words, appliance 26 of Fig. 7 can be implanted appliance 1400 in Fig. 26.

Since Fig. 26 is a cross-sectional view of the oropharyngeal region, for example, looking down from above, only a cross-sectional profile of the generic appliance 1400 (such as appliance 26 of Fig. 7) is shown. However, appliance 26 of Fig. 7, when implanted in the oropharyngeal region 1a, is configured generally as shown in Fig. 7. For example, implanted appliance 26 comprises a substantially C-shaped member 35. Note that the appliance 1400 in Fig. 26 has a generally C-shaped configuration extending across the posterior wall 2d and lateral wall 2b of the oropharyngeal region. The curved, wire struts 36a and 36b

of implanted appliance 26 of Fig. 7 are spaced apart between ends 27, and these wire struts are coupled together or connected at the ends 27. See Fig. 7, and page 29, line 13 to page 30, line 15 of the specification. Thus, although the cross-sectional view of Fig. 26 shows only a profile of an appliance, when the appliance 26 of Fig. 7 is implanted as in Fig. 26, the appliance has two elongated curved elements (36a and 36b) which are longitudinally spaced apart between first and second ends (27) and are coupled together or connected at the ends (27).

Applicant submits that considering elected Figs. 7 and 26 together and with the description set forth in the present specification makes clear that Fig. 26 does facilitate understanding the present invention.

Referring now to the cited prior art, Conrad et al discloses implants for placement in the soft palate and methods for placing such implants in the soft palate.

Conrad et al does not disclose teach or suggest the present invention. For example, Conrad et al does not disclose, teach or even suggest a method for treating at least one of sleep apnea and snoring comprising providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal, as recited in the present method claims.

Conrad et al discloses no implants and methods of placing implants other than soft palate implants and methods for placing such implants in the soft palate. As is well known in the art, the soft palate is a region anatomically and functionally different and distinct from the oropharyngeal region. That the soft palate is different and distinct from the oropharyngeal region is clearly illustrated by the cited Metzger et al

reference at Fig. 1 and related description, for example, paragraph 0029 of the cited Metzger et al reference. In addition, submitted herewith, as Exhibit 1, is a copy of an illustration on page 19 of the CIBA Collection of Medical Illustrations, Vol. 3, Part 1 Upper Digestive Tract (copy of title page attached). Both Fig. 1 of the cited Metzger et al reference and Exhibit 1 make clear that the oropharyngeal region is below the soft palate, is separate and apart from the soft palate and is different and distinct from the soft palate.

Thus, applicant submits that the soft palate implants of Conrad et al when placed in the soft palate, as disclosed by Conrad et al, are not located, and cannot reasonably be interpreted as being located, in or radially outwardly from the lateral and posterior walls of an oropharyngeal region, as in the providing step recited in the present method claims. For example, see Fig. 26 of the above-identified application.

In addition, the soft palate implants and methods of placing such soft palate implants disclosed by Conrad et al are directed toward altering the dynamic response of the soft palate to airflow past the soft palate. See column 2, lines 23-26; column 4, lines 17-21; and column 6, lines 21-23 of Conrad et al. Stiffening the soft palate to alter the dynamic response of the soft palate to airflow pass the soft palate, as disclosed by Conrad et al, is entirely different from and not in the least suggestive of providing an appliance in or radially outwardly from the lateral and posterior walls of a oropharyngeal region of a human or animal, as recited in the present methods claims.

In view of the above, applicant submits that the present claims, and in particular, claims 52-55, 66-68, 70, 71, 73-77,

79 and 80, are not anticipated by and are unobvious from and patentable over Conrad et al under 35 U.S.C. 102(b) and 103.

Metzger et al discloses an implant formed as a braid of a plurality of polyester fibers bonded together near the ends of the braid. Metzger et al discloses that the polyester braided implant is selected to induce a fibrotic tissue response.

Metzger et al does not disclose, teach or suggest the present invention. For example, Metzger et al does not disclose, teach or even suggest an appliance comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle with the two elements being coupled together at respective first and second ends and being spaced apart from each other between the first and second ends, as recited in the present apparatus claims.

In particular, Metzger et al provides no teaching or suggestion whatsoever that the fibers of the polyester braided implant of Metzger et al are spaced apart from each other between the first and second ends. To the contrary, the nature of a braid is such that the individual fibers of the braid are in touching engagement to each other along the length of the braid, rather than being spaced apart from each other. Thus, Metzger et al actually teaches away from an appliance including two elongated curved elements which are spaced apart from each other between first and second ends, as in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 82-90, are not anticipated by and are unobvious from and patentable over Metzger et al under 35 U.S.C. 102(e) and 103.

In addition, it should be noted that certain of the present claims, such as claims 85, 90, 91 and 92 are directed to elements and appliances comprising materials which are not disclosed, taught or even suggested by Metzger et al, and which are not polyesters as disclosed in Metzger et al. For this additional reason, applicant submits that claims 85, 90, 91 and 92 are not anticipated by, and are unobvious from and patentable over Metzger et al under 35 U.S.C. 102(e) and 103.

With regard to the rejection of claim 72, 81, 91 and 92 as being unpatentable over Conrad et al in view of Metzger et al, please consider the following.

Dependent claim 72 discloses a method for treating at least one of sleep apnea and snoring in a human or animal as discussed previously with regard to independent claim 52, and further in which the at least two elements of the appliance are portions of the same structure, are substantially longitudinally spaced apart from each other, and at least one of the elements extends across the posterior wall of the oropharyngeal region.

Dependent claims 81 and 92 are directed to a method and an apparatus for treating at least one of sleep apnea and snoring in a human or animal, as discussed previously with regard to independent claims 52 and 82, and further where the appliance is made of nitinol.

Dependent claim 91 is directed to an apparatus for treating at least one of sleep apnea and snoring in a human or animal, as discussed previously with regard to independent claim 82, and further where the appliance is made of an elastic spring memory material.

As discussed above, Conrad et al teaches the use of implants to alter the dynamic response of the soft palate to airflow past the soft palate.

Metzger et al, on the other hand, discloses a flexible braid of polyester fibers (see paragraph 0042) intended to act as a fibrosis inducing material (see paragraph 0067).

Conrad et al does not disclose, teach or even suggest implants or methods for using implants for placement in the oropharyngeal region. Rather, the Conrad et al implants are placed in the soft palate in the nasopharyngeal region, not in the oropharyngeal region. Metzger et al does not even suggest implants with elements which are connected at first and second ends and are longitudinally spaced apart from each other between the ends.

Neither Conrad et al nor Metzger et al teaches or even suggests the use of implants for use in the oropharyngeal region of a human or animal made of elastic spring memory material or nitinol. In fact, both Conrad et al and Metzger et al teach away from such implants and the use of such implants.

The teachings of Conrad et al directed to soft palate implants and the teachings of Metzger et al directed to a flexible braid of fibrosis inducing polyester fibers are so different and distinct, one from the other, that one of ordinary skill in the art is provided with no motivation or incentive to combine the teachings of these two references for any purpose, let alone for the purpose of making obvious the present invention. Moreover, combining the teachings of Conrad et al and Metzger et al would not provide the methods and apparatus recited in the present claims.

In view of the above, applicant submits that the present claims, and in particular claims 72, 81, 91 and 92, are unobvious from and patentable over Conrad et al in view of Metzger et al under 35 U.S.C. 103.

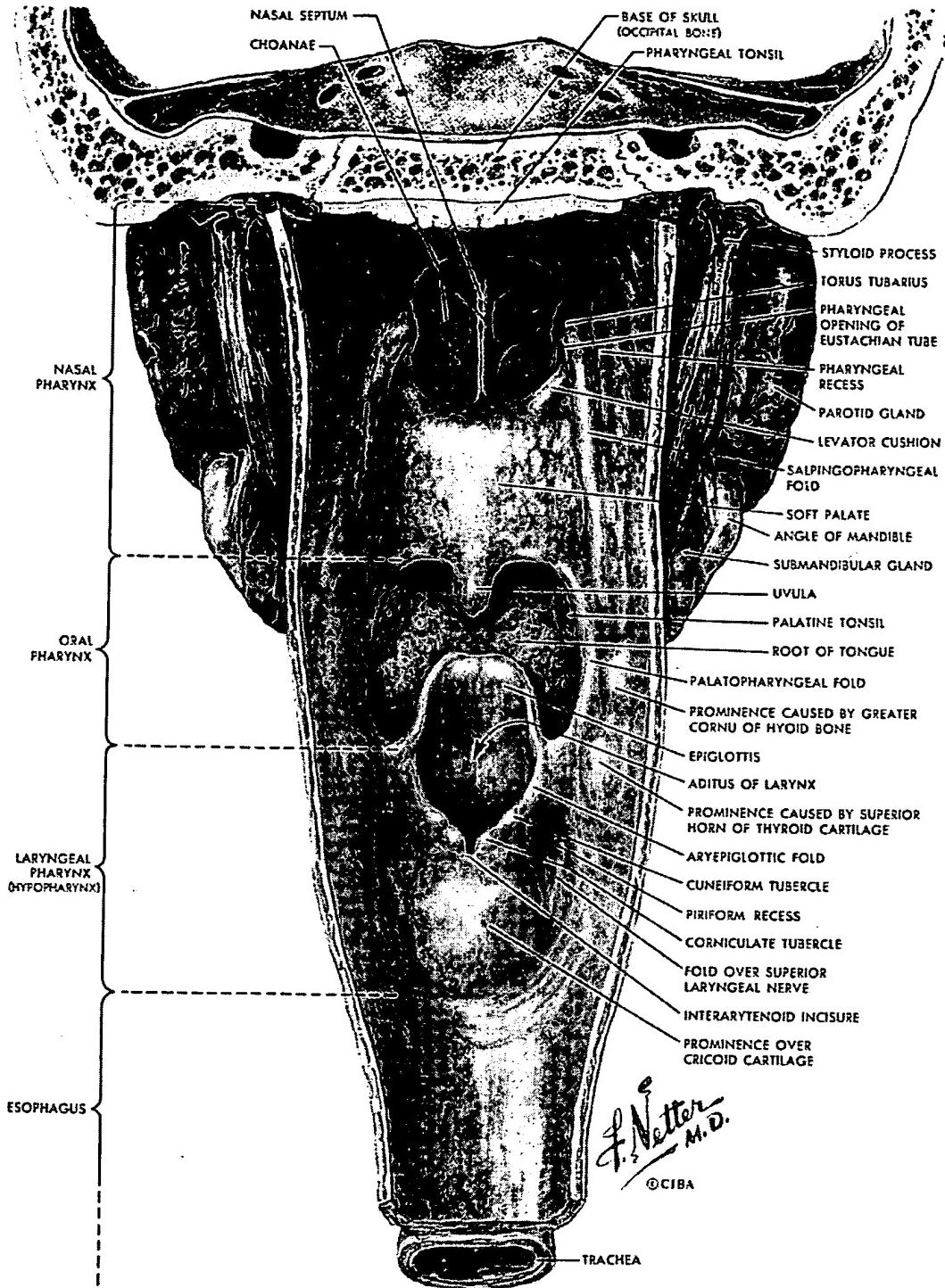
Each of the present dependent claims is separately patentable over the prior art. Each of the present dependent claims is separately patentable over the prior art, taken singly or in any combination. Thus, none of the prior art, taken singly or in any combination disclose, teach or even suggest the methods and apparatus including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

Applicant submits that this reply is fully responsive to the Office Action of February 23, 2006, and that the above-identified application is now in proper order for allowance. Applicant respectfully requests an early and favorable action in the above identified application.

Respectfully submitted,



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From a continuous arched wall, with a slight depression extending from the superior margin of the choanae (where it is continuous with the roof of the nasal cavities) to the midpoint of the basilar portion of the occipital bone; the posterior part extends from this point caudally to the lower border of the anterior arch of the atlas. In the region where the anterior and posterior wall meet, the mucous membrane is thrown into many variable folds, with an accumulation of nodular lymphoid tissue (extensively developed in children, atrophied in adults), forming the pharyngeal tonsil. In the midline near the anterior margin of the pharyngeal tonsil, or immediately behind it, is a minute flask-shaped sac of mucous membrane, known as the pharyngeal bursa. Also in the midline near the anterior limit of the roof, imbedded in the mucosa or lying in the mucous membrane, a microscopic remnant of the "pituitary" (pharyngeal hypophysis) is found, which is grossly visible when it has become cystic or has become a tumor.

The incomplete floor of the nasal pharynx is bounded by the posterosuperior surface of the soft palate with an opening leading to the oral pharynx ("pharyngeal isthmus") between the soft palate and the posterior wall of the pharynx. This opening is closed by bringing these two surfaces in contact.

The lateral wall of the nasal pharynx (see page 16) at the level of the inferior concha is the pharyngeal opening of the auditory tube, with the pharyngeal recess (fossa of Rosenmüller) posterior to it. The prominence of the anterior lip of the opening facilitates introduction of a catheter. The levator veli palatini (produced by the levator veli palatini muscle) bulges into the inferior

margin of the triangular opening, and, coursing inferiortly from the posterior lip, is the salpingopharyngeal fold produced by the muscle of the same name. In childhood a considerable mass of lymphoid tissue (tubal tonsil) may be present in relation to the opening of the auditory tube and may cause deafness.

The oral pharynx extends from the "pharyngeal isthmus" to the level of the pharyngo-epiglottic folds, with the epiglottis protruding into it. In this part of the pharynx, the air and food pathways cross. The posterior wall is in relation to the bodies of the second to fourth cervical vertebrae, while the anterior wall is deficient superiorly where the oral pharynx and oral cavity communicate by means of the faucial isthmus. Below this isthmus the anterior wall is formed by the posterior third of the tongue. Between the tongue and epiglottis are the valleculae (see page 10), where foreign bodies may lodge. (For the struc-

tures of the lateral wall, see pages 15 and 16.)

The laryngeal pharynx (hypopharynx) lies posterior to the larynx and anterior to the fifth and sixth cervical vertebrae. In the cranial part of the anterior wall is the roughly triangular laryngeal aditus, the borders of which are formed by the margins of the epiglottis, the aryepiglottic folds and the interarytenoid incisure. Caudal to this opening the laryngeal pharynx is purely alimentary in function. The mucous membrane of the anterior wall overlies the posterior surfaces of the arytenoid cartilages and the lamina of the cricoid cartilage (mostly covered by laryngeal muscles). Caudal to the laryngo-epiglottic fold on each side is the piriform sinus (recess or fossa), located between the cricoid and arytenoid cartilages medially and the lamina of the thyroid cartilage laterally. This is one of the locations in which foreign bodies may lodge.

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## **DIGESTIVE SYSTEM**

**PART I**

### **UPPER DIGESTIVE TRACT**

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12/12 Annotated Sheet

